2005-7593

October 7, 2005

Dr. Steven K. Galson, M.D., M.P.H.
Department of Health & Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
9200 Corporate Blvd., HFZ-308
Rockville, MD 20850

Dear Dr. Galson:

We would like to thank you for your reply to our petition, Docket No. 2003P-0531/CP1, regarding pill weight tolerances as they relate to counting pills by weight. The detailed and carefully worded reply clearly indicates that considerable thought and effort was put forth and we appreciate your response. While you deny our petition, you have, through your reply, provided us with the conclusions that we would have expected based upon the published weight tolerances as specified in the U.S. Pharmacopeia. We acknowledge your understanding the merits of our request as you so clearly state in the *Discussion* section of your response.

The implied questions we sought answers to, but did not ask directly, were; A). Is it feasible to count pills by weight accurately given single production lot (batch) pill weight tolerances? B). Is it feasible given batch-to-batch pill weight tolerances? You answered both questions in your reply and thereby resolved a significant issue.

The first two sentences of the third paragraph of the *Discussion* section justify our request for information. In the third sentence you state the FDA position on these matters. As stated, the FDA believes that the procedures and requirements of H44, "used in conjunction with appropriate pharmacy QC practices, are sufficient to allow reliable dispensing of tablet and capsule drug products". In the fourth and fifth sentence you outline some supporting H44 requirements for counting by weight. In the sixth sentence (S6), you specified a necessary "pharmacy QC procedure", and you answered our implied questions. It states "To ensure that there is a **reliable** value for dose unit weight, pharmacies using pill weights for dispensing **must**, either at the **time of receipt** of a drug product or **dispensing**, make a **determination of average weight** for the product". This would **allow** the use of an average piece weight based on a sample from within the current supply bottle, and **disallow** the use of a stored average piece weight from a different supply bottle (thereby eliminating the batch-to batch problems). Since H44 allows counting by weight in the pharmacy, a special application, the "QC procedure" (actually an operational directive) as outlined by the FDA should be included in H44 in order to insure proper scale usage. The directive relates directly to a scale function, and there are several ramifications to this "must" requirement of S6. These are detailed in the Attachment No.1.

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We will send copies of your letter along with this letter to both the NCWM and NIST. We will follow up with NCWM and, if necessary, make a presentation to NCWM NE section in order to have the FDA conclusions reflected in H44. The latter process can take several years. We are concerned about informing the pharmacist about the S6 requirement in the interim. Perhaps the FDA could help in this area.

Yours respectfully,

James Q. Maloy

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Attachment No. 1

Suggested Changes to H-44 to rectify scale related problems based on FDA findings:

1. H44 UR.3.12 Correct Stored Weight states "For prescription scales with a counting feature, the user is responsible for maintaining correct stored piece weight. This is especially critical when a medicine has been reformulated or comes from different lots". This wording should be replaced with the exact words of S6. S6 wording, which is both specific and instructive, precludes improper scale usage and eliminates the reformulation problem.
2. H44 table S.6.3.6 note 13 requires scales with a counting function to be marked "counting function is not legal for trade" except for prescription scales. For prescription scales with a counting feature a marking on the scale should be required in order to prevent improper scale usage. The marking shall inform the user of the "must" requirement in a compressed version of S6, such as "user must, either at the time of receipt of a drug product or dispensing, make a determination of APW". If this labeling were made retroactive it would inform users about the requirement for updating the database, including those in scales that came with stored databases.